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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,321	09/02/2003	Robert L. Lawton	BX/TF-101.P.1	3513

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/653,321	LAWTON, ROBERT L.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 November 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 15 November 2005 in which claims 1, 14, 23, 36 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 29 July 2005 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Claims 1-44 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In papers filed 20 May 2005, independent claims 1 and 23 were amended to define the compound of interest and the recognition portion of the binding construct as a "non-nucleic acid". The specification at page 2, ¶ 3, defines the compound of interest as "a non-nucleic acid molecule such as a peptide or protein". The specification further defines the binding construct and its recognition portion as encompassing numerous and various molecules. However the specification does not define or describe the meets and bounds of the non-nucleic acid recognition portion of the binding construct. Therefore, the recitation is not supported by the specification.

In papers filed 15 November 2005, independent claims 1 and 23 were amended to define binding of the compound of interest to the binding construct in step b) and d) as "essentially all" compound being bound. Step d) further define binding of the surface and unbound constructs as "essentially all" unbound constructs being bound. The specification does not describe the meets and bounds of "essentially all" binding. Therefore, the recitation is not supported by the specification.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baez et al (U.S. Patent No. 6,511,809, filed 16 May 2001) in view of Subramanian (U.S. Patent No. 5,244,816, issued 14 September 1993).

Regarding Claim 1, Baez et al teach a method for detecting a non-nucleic acid compound of interest in a sample comprising the steps of (a) providing a binding construct comprising a nucleic acid portion and a non-nucleic acid recognition portion which recognizes and binds (i.e., nucleic acid-tagged antibody) said compound of interest (Column 3, lines 34-41), (b) mixing, in solution, said binding construct with said sample to form construct-compound complexes (Column 12, lines 24-32 and 55-65); removing unbound analytes and detecting the presence or absence of said nucleic acid portion of said binding construct (Column 3, Lines 59-64 and Column 12, lines 33-58 and 66-Column 13, line 17). Baez et al do not teach addition of surface bearing non-nucleic acid binding targets for binding unbound binding constructs.

However, surface bound targets for the removing unbound and labeled binding constructs were well known in the art at the time the claimed invention was made as taught by Subramanian (Abstract). Subramanian teaches the removal of unbound and labeled binding constructs using a surface-bound target provides numerous advantages i.e. "simplicity, highly efficient removal of unbound labeling reagent and economy" (Column 3, lines 30-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the removal of unbound binding constructs as taught by Subramanian to the binding construct-target detection of Baez et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of obtaining a high degree of target specific detection with "simplicity, highly efficient removal of unbound labeling reagent and economy" as taught by Subramanian (Column 3, lines 30-39).

Regarding Claim 2, Subramanian teaches the surface bearing the non-nucleic acid binding targets is selected from matrices e.g. particles, powers, beads (Column 4, lines 31-33).

Regarding Claim 3, Subramanian teaches the surface comprises particles e.g. beads (Column 4, lines 31-33 and Examples 1-8).

Regarding Claim 4, Subramanian teaches the surface comprises particles e.g. beads (Column 4, lines 31-33 and Examples 1-8). And Baez et al teach known immobilization beads comprises particles magnetic (Column 15, lines 6-10).

Regarding Claim 5, Baez et al teach their immobilization surface comprises particles magnetic (Column 15, lines 6-10). While they do not teach a separation step using a magnet, their teaching of a magnetic particle support clearly suggests use of a magnet for separation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a magnet to separate compounds immobilized on the magnetic particles because absent use of a magnet, use of magnetic particles would be meaningless.

Regarding Claim 6, Baez et al teach said detection of the presence or absence of said nucleic acid portion comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 7, Baez et al teach said detection comprises amplification of said nucleic acid via PCR (Column 5, Lines 26-29).

Regarding Claim 8, Baez et al teach said detection comprises amplification of said nucleic acid via PCR (Column 5, Lines 26-29).

Regarding Claim 9, Baez et al teach said detection comprises enzymatic amplification of said nucleic acid via PCR (Column 5, Lines 26-29).

Regarding Claim 10, Baez et al teach said detection of the presence or absence of said nucleic acid portion comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 11, Baez et al teach said amplification comprises PCR (Column 5, Lines 26-29).

Regarding Claim 12, Baez et al teach the method wherein said recognition portion comprises a receptor (Column 7, Lines 54-57).

Regarding Claim 13, Baez et al further teach wherein said recognition portion comprises an antigen (Column 7, Lines 54-57).

Regarding Claim 14, Baez et al teach wherein said recognition portion comprises an antibody (Column 7, Lines 54-57).

Regarding Claim 15, Baez et al teach wherein said recognition portion comprises an antibody (Column 7, Lines 54-57). As previously stated the claim language "comprises a single chain antibody variable region' encompasses additional components (e.g. a complete antibody).

Regarding Claim 16, Baez et al teach the method wherein said recognition portion comprises a Fab fragment (Column 7, Lines 24-26).

Regarding Claim 17, Baez et al teach the method wherein the recognition portion comprises a Fab fragment and the antibody is attached to the nucleic acid via sulfhydryl (Column 24, lines 37-67).

Regarding Claim 18, Baez et al teach the method wherein said compound of interest comprises an antibody, said recognition portion comprises an antigen that is recognized by said compound of interest, and said accessible binding targets comprise an antibody that is capable of recognizing and binding to said recognition portion of said binding construct (Column 11, Line 10 - Column 12, Line 9., Figures 1 and 2).

Regarding Claim 19, Baez et al teach the method wherein said nucleic acid portion comprises DNA (Column 5, Lines 35-37).

Regarding Claim 20, Baez et al teach the method wherein said nucleic acid portion comprises RNA (Column 5, Lines 35-37).

Regarding Claim 21, Baez et al teach wherein said nucleic acid portion comprises a sequence that does not include a sequence that is expected to be found in the sample i.e. they are defined as "reporters" not encoding and/or target molecules (Column 7, Lines 49-57).

Regarding Claim 22, Baez et al teach the method further providing two or more different types of binding constructs, wherein each of said two or more different binding constructs has a different recognition portion and a different nucleic acid portion (Column 15, line 66 - Column 16, Line 3).

Regarding Claim 23, Baez et al teach a method for detecting a non-nucleic acid compound of interest in a sample comprising the steps of (a) providing a binding construct comprising a nucleic acid portion and a non-nucleic acid recognition portion which recognizes and binds (i.e., nucleic acid-tagged antibody) said compound of interest (Column 3, lines 34-41), (b) mixing, in solution, said binding construct with said sample to form construct-compound complexes (Column 12, lines 24-32 and 55-65); removing unbound analytes and detecting the presence or absence of said nucleic acid portion of said binding construct (Column 3, Lines 59-64 and Column 12, lines 33-58 and 66-Column 13, line 17). Baez et al do not teach addition of surface bearing non-nucleic acid binding targets for binding unbound binding constructs.

However, surface bound targets for the removing unbound and labeled binding constructs were well known in the art at the time the claimed invention was made as taught by Subramanian (Abstract). Subramanian teaches the removal of unbound and labeled binding constructs using a surface-bound target provides numerous advantages i.e. "simplicity, highly efficient removal of unbound labeling reagent and economy" (Column 3, lines 30-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the removal of unbound binding constructs as taught by Subramanian to the binding construct-target detection of Baez et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of obtaining a high degree of target specific detection with "simplicity, highly efficient removal of unbound labeling reagent and economy" as taught by Subramanian (Column 3, lines 30-39).

Regarding Claim 24, Subramanian teaches the surface bearing the non-nucleic acid binding targets is selected from matrices e.g. particles, powers, beads (Column 4, lines 31-33).

Regarding Claim 25, Subramanian teaches the surface comprises particles e.g. beads (Column 4, lines 31-33 and Examples 1-8).

Regarding Claim 26, Subramanian teaches the surface comprises particles e.g. beads (Column 4, lines 31-33 and Examples 1-8). And Baez et al teach known immobilization beads comprises particles magnetic (Column 15, lines 6-10).

Regarding Claim 27, Baez et al teach their immobilization surface comprises particles magnetic (Column 15, lines 6-10). While they do not teach a separation step using a magnet, their teaching of a magnetic particle support clearly suggests use of a magnet for separation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a magnet to separate compounds immobilized on the magnetic particles because absent use of a magnet, use of magnetic particles would be meaningless.

Regarding Claim 28, Baez et al teach said detection of the presence or absence of said nucleic acid portion comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 29, Baez et al teach said detection comprises amplification of said nucleic acid via PCR (Column 5, Lines 26-29).

Regarding Claim 30, Baez et al teach said detection comprises amplification of said nucleic acid via PCR (Column 5, Lines 26-29).

Regarding Claim 31, Baez et al teach said detection comprises enzymatic amplification of said nucleic acid via PCR (Column 5, Lines 26-29).

Regarding Claim 32, Baez et al teach said detection of the presence or absence of said nucleic acid portion comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 33, Baez et al teach said amplification comprises PCR (Column 5, Lines 26-29).

Regarding Claim 34, Baez et al teach the method wherein said recognition portion comprises a receptor (Column 7, Lines 54-57).

Regarding Claim 35, Baez et al further teach wherein said recognition portion comprises an antigen (Column 7, Lines 54-57).

Regarding Claim 36, Baez et al teach wherein said recognition portion comprises an antibody (Column 7, Lines 54-57).

Regarding Claim 37, Baez et al teach wherein said recognition portion comprises an antibody (Column 7, Lines 54-57). As previously stated the claim language "comprises a single chain antibody variable region' encompasses additional components (e.g. a complete antibody).

Regarding Claim 38, Baez et al teach the method wherein said recognition portion comprises a Fab fragment (Column 7, Lines 24-26).

Regarding Claim 39, Baez et al teach the method wherein the recognition portion comprises a Fab fragment and the antibody is attached to the nucleic acid via sulfhydryl (Column 24, lines 37-67).

Regarding Claim 40, Baez et al teach the method wherein said compound of interest comprises an antibody, said recognition portion comprises an antigen that is recognized by said compound of interest, and said accessible binding targets comprise an antibody that is capable of recognizing and binding to said recognition portion of said binding construct (Column 11, Line 10 - Column 12, Line 9., Figures 1 and 2).

Regarding Claim 41, Baez et al teach the method wherein said nucleic acid portion comprises DNA (Column 5, Lines 35-37).

Regarding Claim 42, Baez et al teach the method wherein said nucleic acid portion comprises RNA (Column 5, Lines 35-37).

Regarding Claim 43, Baez et al teach wherein said nucleic acid portion comprises a sequence that does not include a sequence that is expected to be found in the sample i.e. they are defined as "reporters" not encoding and/or target molecules (Column 7, Lines 49-57).

Regarding Claim 44, Baez et al teach the method further providing two or more different types of binding constructs, wherein each of said two or more different binding constructs has

a different recognition portion and a different nucleic acid portion (Column 15, line 66 - Column 16, Line 3).

Response to Arguments

7. Applicant asserts that the method of Baez et al is a standard ImmunoPCR method wherein the analyte is captured and multiple wash steps are required to remove unbound reporters. Applicant asserts that the instant method is simple because it does not wash away unbound reporters, but specifically removes them thereby providing the advantages of solution binding of the analyte without subsequent capture, no washing required, removal of unbound binding constructs by specific recognition complexing, and detection of reporter in solution.

Applicant's assertions are noted. However, as cited above, the specific removal of unbound reporters was well known in the art at the time the claimed invention was made. As such, it would have been obvious to one of ordinary skill to apply the reporter specific removal known in the art to the ImmunoPCR method of Baez et al based on the advantages taught by Subramanian i.e. a high degree of target specific detection with "simplicity, highly efficient removal of unbound labeling reagent and economy" (Column 3, lines 30-39).

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
January 30, 2006